



CAROL S. MARCUS, Ph.D., M.D.

MAILING ADDRESS: 1877 COMSTOCK AVENUE
LOS ANGELES, CA 90025-5014

PHONE: (310) 277-4541
FAX: (310) 552-0028
E-MAIL: csmarcus@ucla.edu

Dec. 5, 2018

May Ma
Office of Administration
Mail Stop TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Docket ID NRC-2018-0230

Dear Ms. Ma:

I wish to submit comments about "Training and Experience Requirements for Different Categories of Radiopharmaceuticals", published in the Federal Register on Oct. 29, 2018.

The NRC concept of decreasing requirements for Authorized Users (AUs) for different categories of therapy radiopharmaceuticals is poorly conceived, wrong, dangerous, and misleading. **Follow the money.** The radiopharmaceutical manufacturers believe that by opening up AU status to otherwise unqualified physicians that the manufacturers will make more money. That may well be true, but at the cost of patient and public safety. The NRC staff, ever greedy to increase User Fees to keep their dysfunctional program alive and growing, sees an opportunity to sell more licenses. Their pervasive mantra is "patient access". This is a lie. Patient access is not an issue. Patients who live in small villages or towns may not have access to most medical specialties and are used to traveling to a larger town or city for non-emergency specialist care. That larger town or city will have physicians licensed to perform radiopharmaceutical therapy based upon the requirements of 10 CFR Part 35.390.

The NRC is concerned with radiation safety of patients, members of the public, and the environment. It takes a long time to learn all the aspects of safe use of therapy radiopharmaceuticals, and "quickie" courses don't cut it. The current 80-hour training program is grossly insufficient to educate physicians in all the aspects of the use of I-131 NaI or parenterally administered therapy radiopharmaceuticals. In 1994, going into a redo of Part 35, the ACMUI voted unanimously to recommend that NRC get rid of the 80-hour training program which was started by the Atomic Energy Commission after World War II and which had long outlived its usefulness. The NRC ignored the ACMUI. However, the 80 hours simply isn't enough time to learn all the necessary material. The necessary material has been itemized and submitted to the NRC by the Society of Nuclear

Medicine and Molecular Imaging (SNMMI), the American College of Nuclear Medicine (ACNM), and the American Society for Radiation Oncology (ASTRO) in a letter submitted to the NRC dated July 10, 2018. Presumably the “quickie” courses NRC staff has in mind, while not described in the Federal Register notice, would be even shorter than the 80-hour training program.

A case around 2005 shows what happens when a physician is not adequately educated, trained, and experienced in the use of I-131 NaI. A radiologist who was not board certified in nuclear medicine administered a large therapy dose of I-131 NaI to a dying patient with thyroid cancer who was an inpatient and who was in complete renal failure and not on dialysis. The physician then promptly left town for a three day weekend, and neither he nor any other Authorized User (AU) physician was available to care for the patient. The patient’s daughter refused to leave her dying mother’s bedside, despite repeated urgings by the Radiation Safety Officer (RSO) that the daughter’s radiation dose would exceed legal limits. A competent physician would never abandon a patient like that without coverage by another qualified physician. A competent physician would know that you never give therapy doses of radiopharmaceuticals to dying patients, as you don’t cure anything and end up with a radioactive corpse. A competent physician would not have given anything like the large dose that was used in a patient with complete renal failure and not on dialysis. The patient died several days later. However, had the patient survived, she would likely have died from bone marrow failure due to the very large bone marrow dose from the I-131. Did the NRC take away the radiologist’s AU status? No. The hospital fired the RSO instead. Disgusting.

If the NRC thinks that it is not important for physicians to learn much about radiation safety because the radioactive material used in radiopharmaceutical therapy is not really dangerous, then why do we even bother to have NRC’s Medical Program? Who needs it? There is no lower limit to the level of medical quality, and the NRC appears to be racing to the bottom at top speed. The NRC is a clear and present danger to patient health and safety.

I urge the Commissioners to stop its staff from continuing work on this dangerous enterprise.

Thank you for your attention and consideration.

Sincerely,



Carol S. Marcus, Ph.D., M.D., ABNM, FACNM
Professor of Radiation Oncology, of Molecular and Medical Pharmacology (Nuclear Medicine), and of Radiological Sciences, ret., David Geffen School of Medicine at UCLA

Member of the ACMUI 1990-1994

CHAIRMAN Resource

From: Carol Marcus <csmarcus@ucla.edu>
Sent: Wednesday, December 05, 2018 7:50 PM
To: CMRBurns Resource; CMRBARAN Resource; CHAIRMAN Resource; CMRCaputo Resource; CMRWright Resource
Cc: Munir Ghesani; czernin johannes; Aria Razmaria; Abreu, Sue
Subject: [External_Sender] Physician T&E Comment Letter
Attachments: NRC T&E 12-05-18.docx

Dec. 5, 2018

Dear Commissioners:

I would be most grateful if you would review that attached comment letter.

Thank you.

Sincerely,

Carol S. Marcus, Ph.D., M.D.